

AMENDMENT TO THE CLAIMS

The listing of claims below will replace all prior versions and listings of claims in the application:

Claims 1-3 Cancelled

4. (Currently amended) The solid unit dosage form of Claim ~~394~~ wherein said atorvastatin or pharmaceutically acceptable salt thereof is a form of atorvastatin that is at least somewhat disordered or a mixture of crystalline and disordered forms of atorvastatin.

Claims 5-7 Cancelled

8. (Currently amended) The solid unit dosage form of atorvastatin according to Claim ~~394~~ wherein said unit dosage form contains not more than about 2% total drug related impurities and/or degradants based on the area percent of the impurities and/or degradants relative to the integrated area of all drug related peaks as determined by HPLC.

9. (Currently amended) The solid unit dosage form of atorvastatin according to Claim ~~394~~ wherein said unit dosage form contains not more than about 2% atorvastatin lactone based on the area percent of the lactone peak relative to the integrated area of all drug related peaks as determined by HPLC.

10. (Currently amended) The solid unit dosage form of atorvastatin according to Claim ~~394~~ wherein said unit dosage form, after storage at 40°C and 75% relative humidity for 4 weeks, contains not more than about 1% total drug related impurities and/or degradants based on the area percent of all drug related peaks relative to the area of the atorvastatin peak as determined by HPLC.

11. (Currently amended) The solid unit dosage form of atorvastatin according to Claim ~~39~~ wherein said unit dosage form, after storage at 40°C and 75% relative humidity for 4 weeks, contains not more than about 1% atorvastatin lactone based on the area percent of the lactone peak relative to the integrated area of all drug related peaks as determined by HPLC.

12. (Currently amended) The solid unit dosage form of Claim ~~39~~, wherein the composition formed from said excipient or combination of excipients and said atorvastatin or a pharmaceutically acceptable salt thereof has a segregation number of less than 0.6 when tested with a fluidization segregation tester.

Claims 13-17 Cancelled.

Claims 18-30 Cancelled

31. (Currently Amended) The solid unit dosage form according to claim ~~39~~ wherein said alkalinizing agent is selected from the group consisting of inorganic bases and organic bases.

32. (Previously Added) The solid unit dosage form according to claim 31 which contains less than 5 w/w% of a polymeric amide or polymeric amine.

33. (Previously Added) The solid unit dosage form according to claim ~~39~~ that contains less than 2 w/w% of said alkalinizing agent.

34. (Previously Added) The solid unit dosage form according to claim 33 wherein said alkalinizing agent is selected from the group consisting of inorganic bases and organic bases.

35. (Previously Added) The solid unit dosage form according to claim 34 which contains less than 3 w/w% of a polymeric amide or polymeric amine.

36. (Previously Added) The solid unit dosage form according to claim 39+ that contains less than 1 w/w% of said alkalinizing agent.

37. (Previously Added) The solid unit dosage form according to claim 36 wherein said alkalinizing agent is selected from the group consisting of inorganic bases and organic bases.

38. (Previously Added) The solid unit dosage form according to claim 37 which contains less than 2 w/w% of a polymeric amide or polymeric amine.

39. (New) A solid unit dosage form comprising:

- a) atorvastatin, or a pharmaceutically acceptable salt thereof, in which said atorvastatin has a mean particle size between 1 and 100 μm ,
- b) one, or more, diluents in which at least 50% by weight of said diluents have a mean particle size between 8 and 360 μm ,
- c) said unit dosage form is a tablet prepared by direct compression without a granulation step,
- d) wherein the measured atorvastatin potency of said dosage form shows a relative standard deviation for atorvastatin potency per unit dosage form of not more than about 7.8%, when said unit dosage form is prepared at a rate greater than 10,000 unit dosage forms per hour per single unit dosage form per machine, and;
- e) said solid unit dosage form contains less than 5 w/w% of an alkalizing agent additive.

40. (New) The solid unit dosage form according to claim 39 in which said atorvastatin is amorphous.

41. (New) The solid unit dosage form according to claim 39 in which said diluents has a mean particle size between 90 and 280 μm .

42. (New) The solid unit dosage form according to claim 39 in which at least 70% of said diluents has a mean particle size between 8 and 360 μm .

43. (New) The solid unit dosage form according to claim 39 in which said diluents has a mean particle size between 90 and 280 μm .

44. (New) The solid unit dosage form according to claim 39 in which at least 70% of said diluents has a mean particle size between 90 and 280 μm .